

**INFORMATION
DISCLOSURE
STATEMENT**

Atty. Docket No.: 180.00030102

Serial No.: 09/814,257

Applicant(s): Hanson et al.

Confirmation No.: 6204

Filing Date: March 21, 2001

Group: 1655

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U.S. PATENT DOCUMENTS

Examiner Initial	Patent Number	Date	Name	Class	Subclass	Filing Date If Appropriate
W	—	4,683,194	07/28/87	Saiki et al.		
	—	4,683,195	07/28/87	Mullis et al.		
	—	5,994,066	11/30/99	Bergeron et al.		
	—	6,001,564	12/14/99	Bergeron et al.		
↓	—	6,242,223	06/05/01	Hanson et al.		

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FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
none		X			Yes No
		X			

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

W	Acar et al., "Nature of the Resistance Problem," <u>Clin. Inf. Dis.</u> , 24(Suppl 1):S1 (1997).
	Arlet et al., "Construction by polymerase chain reaction and intragenic DNA probes for three main types of transferable β -lactamases (TEM, SHV, CARB)," <u>FEMS Microbiol. Lett.</u> , 82:19-25 (1991).
	Arlet et al., "Molecular characterization by PCR-restriction fragment length polymorphism of TEM β -lactamases," <u>FEMS Microbiol. Lett.</u> , 134:203-208 (1995).
	Arlet et al., "Substitution of alanine for aspartate at position 179 in the SHV-6 extended-spectrum β -lactamase," <u>FEMS Microbiol. Lett.</u> , 152:163-167 (1997).
	Barnaud et al., "Cloning and sequencing of the gene encoding the AmpC β -lactamase of <i>Morganella morganii</i> ," <u>FEMS Microbiol. Lett.</u> 148:15-20 (1997).
	Bauernfeind et al., "A New Plasmidic Cefotaximase in a Clinical Isolate of <i>Escherichia coli</i> ," <u>Infection</u> , 18(5):294-298 (1990).
↓	Billot-Klein et al., "Nucleotide Sequence of the SHV-5 β -Lactamase Gene of a <i>Klebsiella pneumoniae</i> Plasmid," <u>Antimicrob. Agents Chemother.</u> , 34(12):2439-2441 (1990).

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Date Considered

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u	—	Birnboim et al., "A rapid alkaline extraction procedure for screening recombinant plasmid DNA," <u>Nucleic Acids Res.</u> , <u>7</u> (6):1513-1523 (1979).
	—	Bradford et al., "SHV-7, a Novel Cefotaxime-Hydrolyzing β -Lactamase, Identified in <i>Escherichia coli</i> Isolates from Hospitalized Nursing Home Patients," <u>Antimicrob. Agents Chemother.</u> , <u>39</u> (4):899-905 (1995).
	—	Bradford et al., "Multiply Resistant <i>Klebsiella pneumoniae</i> Strains from Two Chicago Hospitals: Identification of the Extended-Spectrum TEM-12 and TEM-10 Cefotaxime-Hydrolyzing β -Lactamases in a Single Isolate," <u>Antimicrob. Agents Chemother.</u> , <u>38</u> (4): 761-766 (1994).
	—	Bret et al., "Chromosomally Encoded AmpC-Type β -Lactamase in a Clinical Isolate of <i>Proteus mirabilis</i> ," <u>Antimicrob. Agents Chemother.</u> , <u>42</u> (5):1110-1114 (1998).
	—	Brun-Buisson et al., "Transferable Enzymatic Resistance to Third-Generation Cephalosporins During Nosocomial Outbreak of Multiresistant <i>Klebsiella pneumoniae</i> ," <u>The Lancet</u> , <u>2</u> :302-306 (1987).
	—	Burns et al., "An Integrated Nanoliter DNA Analysis Device," <u>Science</u> , <u>282</u> :484-487 (1998).
	—	Canica et al., "Molecular Diversity and Evolution of <i>bla</i> _{tem} Genes Encoding β -Lactamases Resistant to Clavulanic Acid in Clinical <i>E. coli</i> ," <u>J. Mol. Evol.</u> , <u>44</u> :57-65 (1997).
	—	Carter et al., "Use of a non-radioactive hybridisation assay for direct detection of gram-negative bacteria carrying TEM β -lactamase genes in infected urine," <u>J. Med. Microbiol.</u> , <u>28</u> :113-117 (1989).
	—	Check, "Clinical Microbiology Eyes Nucleic Acid-Based Technologies," <u>ASM News</u> , <u>64</u> (2):84-89 (1998).
	—	Crea et al., "Chemical synthesis of genes for human insulin," <u>Proc. Natl. Acad. Sci. USA</u> , <u>75</u> (12):5765-5769 (1978).
	—	Crosa et al., "Plasmids," <u>Manual of Methods for General Bacteriology</u> , Gerhardt et al., eds., American Society for Microbiology, Washington, DC, Ch.15, pgs. 266-282 (1981).
↓	—	Curran et al., "A rapid immunoassay method for the direct detection of PCR products: application to detection of TEM β -lactamase genes," <u>J. Med. Microbiol.</u> , <u>45</u> :76-78 (1996).

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AUG 21 2001

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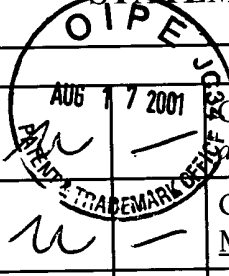
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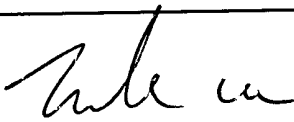
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	Galleni et al., "Sequence and comparative analysis of three <i>Enterobacter cloacae</i> AmpC β -lactamase genes and their products," <u>Biochem. J.</u> , <u>250</u> , 753-760 (1988).
u	Gold et al., "Antimicrobial-Drug Resistance," <u>The New England Journal of Medicine</u> , <u>335</u> (19):1445-1453 (1996).
	Gonzalez Leiza et al., "Gene sequence and biochemical characterization of FOX-1 from <i>Klebsiella pneumoniae</i> , a new AmpC-type plasmid-mediated beta-lactamase with two molecular variants," <u>Antimicrob. Agents Chemother.</u> , <u>38</u> (9):2150-7 (1994).
	Hanson et al., "Molecular Characterization of a Multiply Resistant <i>Klebsiella pneumoniae</i> ," Abstract C-59, <u>37th ICAAC</u> , Toronto, Ontario, Canada, September 28-October 1 (1997).
	Hanson et al., "A Novel TEM-Type Extended Spectrum Beta-Lactamase Expressed in Three Different Genera of Enterobacteriaceae from South Africa," Abstract C-5, pg 70, <u>38th ICAAC</u> , San Diego, California, September 24-27 (1998).
	Hanson et al., "Molecular characterization of a multiply resistant <i>Klebsiella pneumoniae</i> encoding ESBLs and a plasmid-mediated AmpC," <u>J. Antimicrob. Chemother.</u> , <u>44</u> :377-380 (1999).
	Hanson et al., "Regulation of Inducible AmpC Beta-Lactamase Expression Among Enterobacteriaceae," <u>Curr. Pharmac. Design</u> , <u>5</u> (11):881-894 (1999).
	Hibbert-Rogers et al., "Convergent evolution of TEM-26, a β -lactamase with extended-spectrum activity," <u>J. Antimicrob. Chemother.</u> , <u>33</u> :707-720 (1994).
	Huletsky et al., "Nucleotide Sequence and Phylogeny of SHV-2 β -Lactamase," <u>Antimicrob. Agents Chemother.</u> , <u>34</u> (9):1725-1732 (1990).
	Jacoby et al., "More Extended-Spectrum β -Lactamases," <u>Antimicrob. Agents Chemother.</u> , <u>35</u> (9):1697-1704 (1991).
	Jarlier et al., "Extended Broad-Spectrum β -Lactamases Conferring Transferable Resistance to Newer β -Lactam Agents in Enterobacteriaceae: Hospital Prevalence and Susceptibility Patterns," <u>Rev. Infect. Dis.</u> , <u>10</u> (4):867-878 (1988).
↓	Jones, "The Emergent Needs for Basic Research, Education, and Surveillance of Antimicrobial Resistance: Problems Facing the Report from the American Society for Microbiology Task Force on Antibiotic Resistance," <u>Diagn. Microbiol. Infect. Disease</u> , <u>25</u> :153-161 (1996).

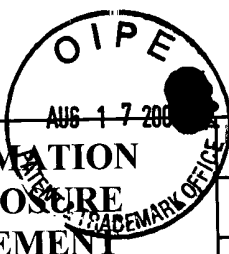
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u	—	Jones, "Important and Emerging β -Lactamase-mediated Resistances in Hospital-based Pathogens: The Amp C Enzymes," <u>Diagn. Microbiol. Infect. Dis.</u> , 31:461-466 (1998).
	—	Leung et al., "Rarity of transferable β -lactamase production by <i>Klebsiella</i> species," <u>J. Antimicrob. Chemother.</u> , 39:737-745 (1997).
	—	M'Zali et al., "Brief reports: Detection of mutations conferring extended-spectrum activity on SHV β -lactamases using polymerase chain reaction single strand conformational polymorphism (PCR-SSCP)," <u>J. Antimicrob. Chemother.</u> , 37:797-802 (1996).
	—	Mabilat et al., "Direct Sequencing of the Amplified Structural Gene and Promoter for the Extended-Broad-Spectrum β -Lactamase TEM-9 (RHH-1) of <i>Klebsiella pneumoniae</i> ," <u>Plasmid</u> , 23:27-34 (1990).
	—	Mabilat et al., "Development of "Oligotyping" for Characterization and Molecular Epidemiology of TEM β -Lactamases in Members of the Family <i>Enterobacteriaceae</i> ," <u>Antimicrob. Agents Chemother.</u> , 34(11):2210-2216 (1990).
	—	Maniatis et al., <u>Molecular Cloning: A Laboratory Manual</u> , Cold Spring Harbor, NY (Title page, Publication page, and Table of Contents only) 8 pgs. (1982).
	—	Marchese et al., "Characterization of FOX-3, an AmpC-Type Plasmid-Mediated β -Lactamase from an Italian Isolate of <i>Klebsiella oxytoca</i> ," <u>Antimicrob. Agents Chemother.</u> , 42(2):464-467 (1998).
	—	Martineau, Species-specific and ubiquitous DNA-based assays for rapid identification of <i>Staphylococcus epidermidis</i> ," <u>J Clin Microbiol.</u> , 34(12):2888-93 (1996).
	—	Medeiros, "Recent Increases in Resistance: Mechanisms and Organisms: Evolution and Dissemination of β -Lactamases Accelerated by Generations of β -Lactam Antibiotics," <u>Clin. Inf. Dis.</u> , 24(Suppl 1):S19-45 (1997).
	—	Mercier et al., "Cloning of SHV-2, OHIO-1, and OXA-6 β -Lactamases and Cloning and Sequencing of SHV-1 β -Lactamase," <u>Antimicrob. Agents Chemother.</u> , 34(8):1577-1583 (1990).
✓	—	Mugnier et al., "A TEM-Derived Extended-Spectrum β -Lactamase in <i>Pseudomonas aeruginosa</i> ," <u>Antimicrob. Agents Chemother.</u> , 40(11):2488-2493 (1996).

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AUG 21 2001

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9/6/2002

TECH CENTER 1600/2900

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u	—	Mullis et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," <u>Cold Spring Harbor Symposia on Quantitative Biology</u> , Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, <u>51</u> :263-273 (1986).
	—	Mullis et al., "Specific Enzymatic Amplification of DNA <i>In Vitro</i> : The Polymerase Chain Reaction," <u>Milestones in Biotechnology: Classic Papers on Genetic Engineering</u> , Davies et al., eds., Buterworth-Heinemann, Stoneham, MA, pp. 17-27 (1992).
	—	Naumovski et al., "Outbreak of Ceftazidime Resistance Due to a Novel Extended-Spectrum β -Lactamase in Isolates from Cancer Patients," <u>Antimicrob. Agents Chemother.</u> , <u>36</u> (9):1991-1996 (1992).
	—	Nordmann et al., "Characterization of a Novel Extended-Spectrum β -Lactamase from <i>Pseudomonas aeruginosa</i> ," <u>Antimicrob. Agents Chemother.</u> , <u>37</u> (5): 962-969 (1993).
	—	Nüesch-Inderbinnen et al., "Detection of Genes Coding for Extended-Spectrum SHV Beta-Lactamases in Clinical Isolates by a Molecular Genetic Method, and Comparison with the E Test," <u>Eur. J. Clin. Microbiol. Infect. Dis.</u> , <u>15</u> :398-402 (1996)
	—	O'Callaghan et al., "Inhibition of β -Lactamase Decomposition of Cephaloridine and Cephalothin by Other Cephalosporins," <u>Antimicrob. Agents Chemother.</u> , 337-343 (1967).
	—	Philippon et al., "Minireview -- Extended-Spectrum β -Lactamases," <u>Antimicrob. Agents Chemother.</u> , <u>33</u> (8):1131-1136 (1989).
	—	Piddock et al., "Prevalence and mechanism of resistance to 'third-generation' cephalosporins in clinically relevant isolates of Enterobacteriaceae from 43 hospitals in the UK, 1990-1991," <u>J. Antimicrob. Chemother.</u> , <u>39</u> :177-187 (1997).
	—	Pitout et al., " β -Lactamases Responsible for Resistance to Expanded-Spectrum Cephalosporins among <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> and <i>Proteus mirabilis</i> Isolates Recovered in South Africa," <u>96th ASM General Meeting</u> , Poster and Abstract A-46, p.141 (May 1996).
↓	—	Pitout et al., " β -Lactamases Responsible for Resistance to Expanded-Spectrum Cephalosporins in <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> , and <i>Proteus mirabilis</i> Isolates Recovered in South Africa," <u>Antimicrob. Agents Chemother.</u> , <u>42</u> (6):1350-1354 (1998).

RECEIVED

EXAMINER

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<u>m</u>	—	Pitout et al., "Plasmid-Mediated Resistance to Expanded-Spectrum Cephalosporins among <i>Enterobacter aerogenes</i> Strains," <u>Antimicrob. Agents Chemother.</u> , <u>42</u> (3):596-600 (1998).
	—	Prodinger et al., "Molecular Epidemiology of <i>Klebsiella pneumoniae</i> Producing SHV-5 β -Lactamase: Parallel Outbreaks Due to Multiple Plasmid Transfer," <u>J. Clin. Microbio.</u> , <u>34</u> (3):564-568 (1996).
	—	Resigner PCR from Research Genetics. Advertisement in <u>Nucleic Acids Res.</u> , <u>22</u> (15)
	—	Saiki et al., "Enzymatic Amplification of β -Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," <u>Science</u> , <u>230</u> , 1350-1354 (1985).
	—	Saiki et al., "Analysis of enzymatically amplified β -globin and HLA-DQ α DNA with allele-specific oligonucleotide probes," <u>Nature</u> , <u>324</u> :163-166 (1986).
	—	Sanchez et al., "The E-Test Applied to Susceptibility Tests of Gonococci, Multiply-Resistant Enterococci, and Enterobacteriaceae Producing Potent β -Lactamases," <u>Diagn. Microbiol. Infect. Dis.</u> , <u>15</u> :459-463 (1992).
	—	Sanders et al., "New Service Notification," distributed by Center for Research in Anti-Infectives and Biotechnology, Creighton University School of Medicine (September 28, 1997)
	—	Sanders et al., "Characterization of β -Lactamases In Situ on Polyacrylamide Gels," <u>Antimicrob. Agents Chemother.</u> , <u>30</u> (6):951-952 (1986).
	—	Sanders, Jr. et al., " <i>Enterobacter</i> spp.: Pathogens Poised To Flourish at the Turn of the Century," <u>Clin. Microbiol. Rev.</u> , <u>10</u> (2):220-241 (1997).
	—	Sayeed et al., "Expression of <i>Aeromonas caviae</i> <i>bla</i> genes in <i>Escherichia coli</i> ," <u>J. Antimicrob. Chemother.</u> , <u>38</u> :435-441 (1996).
	—	Scharf et al., "Direct Cloning and Sequence Analysis of Enzymatically Amplified Genomic Sequences," <u>Science</u> , <u>233</u> , 1076-1078 (1986).
	—	Schmitz et al., "Specific information concerning taxonomy, pathogenicity and methicillin resistance of staphylococci obtained by a multiplex PCR," <u>J. Med. Microbiol.</u> , <u>46</u> :773-778 (1997).
	—	Sirot et al., "A Complex Mutant of TEM-1 β -Lactamase with Mutations Encountered in Both IRT-4 and Extended-Spectrum TEM-15, Produced by an <i>Escherichia coli</i> Clinical Isolate," <u>Antimicrob. Agents Chemother.</u> , <u>41</u> (6):1322-1325 (1997).

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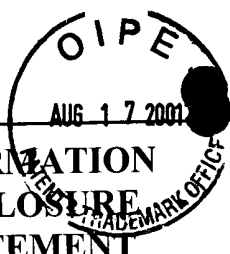
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<i>m</i>	—	Sutcliffe, "Nucleotide sequence of the ampicillin resistance gene of <i>Escherichia coli</i> plasmid pBR322," <u>Proc. Natl. Acad. Sci. USA</u> , <u>75</u> (8):3737-3741 (1978).
	—	Tenover et al., "Development of PCR Assays to Detect Ampicillin Resistance Genes in Cerebrospinal Fluid Samples Containing <i>Haemophilus influenzae</i> ," <u>J. Clin. Microb.</u> , <u>32</u> (11):2729-2737 (1994).
	—	Tenover et al., "SHEA Position Paper: How to Select and Interpret Molecular Strain Typing Methods for Epidemiological Studies of Bacterial Infections: A Review for Healthcare Epidemiologists," <u>Infect. Control and Hosp. Epidemiol.</u> , <u>18</u> (6):426-439 (1997).
	—	Thomson et al., "High-Level Resistance to Cefotaxime and Ceftazidime in <i>Klebsiella pneumoniae</i> Isolates from Cleveland, Ohio," <u>Antimicrob. Agents Chemother.</u> , <u>35</u> (5):1001-1003 (1991).
	—	Thomson et al., "Detection of Extended-Spectrum β -Lactamases in Members of the Family <i>Enterobacteriaceae</i> : Comparison of the Double-Disk and Three-Dimensional Tests," <u>Antimicrob. Agents Chemother.</u> , <u>36</u> (9):1877-1882 (1992).
	—	Tolmasky, "Sequencing and Expression of <i>aadA</i> , <i>bla</i> , and <i>tnpR</i> from the Multiresistance Transposon Tn1331," <u>Plasmid</u> , <u>24</u> , 218-226 (1990).
	—	Towner, "Leading article: Detection of antibiotic resistance genes with DNA probes," <u>J. Antimicrob. Chemother.</u> , <u>30</u> :1-2 (1992).
	—	Vercauteren et al., "Comparison of Screening Methods for Detection of Extended-Spectrum β -Lactamases and Their Prevalence among Blood Isolates of <i>Escherichia coli</i> and <i>Klebsiella</i> spp. in a Belgian Teaching Hospital," <u>J. Clin. Microb.</u> , <u>35</u> (9):2191-2197 (1997).
	—	Walsh et al., "Sequence analysis of two chromosomally mediated inducible β -lactamases from <i>Aeromonas sobria</i> , strain 163a, one a class D penicillinase, the other an AmpC cephalosporinase," <u>J. Antimicrob. Chemother.</u> , <u>36</u> : 41-52 (1995).
↓	—	Zhou et al., "Emergence of Clinical Isolates of <i>Escherichia coli</i> Producing TEM-1 Derivatives or an OXA-1 β -Lactamase Conferring Resistance to β -Lactamase Inhibitors," <u>Antimicrob. Agents Chemother.</u> , <u>38</u> (5):1085-1089 (1994).

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AUG 21 2001

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